

## REMARKS

In the Office Action mailed from the United States Patent and Trademark Office on November 9, 2009, claims 1-2 and 7-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,250,035 to Smith et al. ("Smith") in view of U.S. Patent Publication No. 2002/0123723 to Sorenson et al. ("Sorenson"); and claims 3-6 were rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. and Sorenson in further view of U.S. Patent Publication No. 2002/055715 to Young et al. ("Young").

Claims 1, 5, and 7 are currently amended, and claims 10-12 are new. Support for the amendments and new claims may be found at least at page 8 lines 11-15.

### **Rejections under 35 U.S.C. 103**

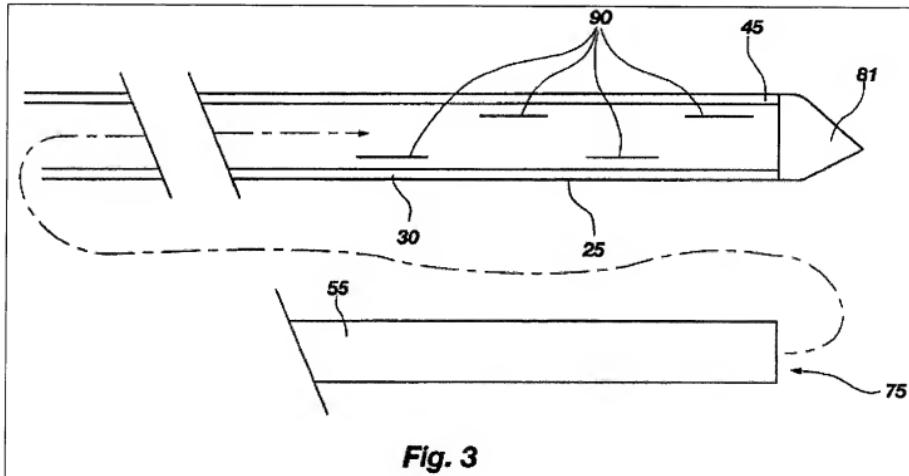
Claims 1, 2 and 7-9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No 5,250,035 ("Smith") in view of U.S. Patent Publication No. 2002/0123723 ("Sorenson"). Applicant respectfully submits that the cited references, alone or in combination, do not teach or suggest all the limitations recited in the claim set provided herein. In particular independent claims 1, 5 and 7 contain limitations drawn to a hollow needle having a plurality of fenestrations wherein the fenestrations are spaced at intervals within two millimeters of each other. The plurality of fenestrations as claimed provides the unexpected benefit of allowing a method for properly locating and anesthetizing a fascial compartment containing a nerve while avoiding intravascular injection and/or inadvertent penetration of the affected nerve. Smith's disclosure related to a spinal catheter and Sorenson's disclosure related to a method for diffusing medication in a subcutaneous injection fail to read on the peripheral nerve block needle of the present application.

The differences between the claimed invention and the cited references are important and striking, and one of skill in the art would not find it obvious to overcome the differences to arrive at the claimed invention. The differences between various types of needles call for differing structures and the differing structures greatly affect their suitability for differing uses. For

example, using the spinal catheter system of Smith for providing a nerve block procedure would be extraordinarily difficult due to the difficulties in placing the needle outlet of Smith within the facial compartment. Reference may be made to Smith's description of use of the cannula beginning at column 4 line 53. The procedure starts with an introducer making an initial passage or puncture that terminates adjacent the dura. (Col. 4 lines 60-64; Col. 3 lines 23-26) The system of Smith is then advanced slightly to part the dura to access the subarachnoid space. (Col. 4 lines 62-69; Col. 5 lines 6-10) One of skill in the art would thus understand that the system of Smith is not properly intended for blind placement of the cannula deep within tissue, but is instead to be used for the final advancement stage just through the dura itself. This final placement procedure is very different from the nerve block usage of the presently-claimed invention, and those differences provide significant benefits for nerve block procedures.

Similarly, the tubular medication dispersal system of Sorenson is for a very different situation than the nerve block procedure of the presently-claimed invention, and these differences are notable in the differences between the system described by Sorenson and the claimed invention. The system of Sorenson utilizes perforations or striations structured and arranged to achieve substantially-uniform volume and rate of dispersion of therapeutic fluids cylindrically along the perforated length of the tube. (Col. 3 lines 64-67; Col. 6 lines 35-37) The system of Sorenson is designed for delivery of medication subcutaneously or interstitially. (Abstract, Col. 1 lines 17-20) Thus, the system disclosed in Sorenson is designed for broad and even dispersal of the medication through the system, and one of skill in the art would understand its design as achieving this goal. It should be noted that Sorenson describes the desirable size of striations to achieve this goal, indicating that the striations (shown in Figure 3 at reference number 90, shown for reference on the next page below) should be approximately 5 millimeters in length in one preferred embodiment and approximately 1 centimeter in length in the second preferred embodiment. Figure 3 may be referenced to show that the striations are spaced at approximately their own length. As this is Sorenson's only teaching with respect to the size and spacing of the striations/perforations, Applicant respectfully notes that Sorenson fails to teach the

claimed fenestrations spaced at intervals within two millimeters of each other as is required by the claims.



**Fig. 3**

Because of the different anticipated uses between the claimed invention and the devices disclosed in the cited references, one of skill in the art would not find it obvious to modify those references to change the approximately 5 millimeter spacing of Sorenson to the claimed fenestrations having spacing at intervals within two millimeters of each other. While the Sorenson device is designed to apply medicine uniformly around all the Sorenson openings, the claimed nerve block needle apparatus is designed to position one or two fenestrations within a facial compartment (which can be very narrow) while the remaining fenestrations are within the muscle. In this use, the flow through the intra-muscular fenestrations is relatively low while the flow within the facial compartment is higher. (See specification as filed, page 8 line 18 through page 9 line 11.) If a needle having the spacing disclosed in Sorenson (for general pain medicine

administration, not for peripheral nerve blocks) were used to attempt a nerve block as disclosed in the present application, the attempt would likely fail due to the high likelihood that access to the facial compartment would not be achieved.

Although the differences between Sorenson and the claimed invention are subtle, Applicant respectfully submits that the differences are extremely important and that one of skill in the medical arts would not find it obvious to modify Sorenson to arrive at the claimed invention. Therefore, for at least these reasons, the claims are not made obvious by the combinations of references including Smith and Sorenson.

Additionally, with respect to method claim 7, Applicant respectfully notes that none of the cited references disclose the method steps required by the claim. Specifically, claim 7 requires: “advancing said fenestrated needle slowly through said dermal area and said facial membrane, whereby at least one of said fenestrations is located within said facial compartment,” and “injecting local anesthetic through said fenestrated needle to induce an efflux of local anesthetic into said facial compartment while minimizing flow of anesthetic outside the boundaries of the fascial compartment and a corresponding anesthetic block at said affected peripheral nerve.” Such features are not taught by any of the cited references, which fail to disclose or discuss any features with respect to facial compartments. Therefore, for this additional reason, method claim 7 is not made obvious by the cited references, and its dependent claims are similarly allowable.

Because the combination of art does not teach every limitation of the claimed invention, and because one of skill in the art would not find it obvious to modify the art to overcome the differences between the art and the claimed invention, Applicant respectfully requests that the obviousness rejections be withdrawn.

Applicant wishes to hasten allowance of the application, and requests a telephonic interview with the Examiner at the Examiner’s convenience upon receipt of this communication and continued examination under 37 C.F.R. § 1.114.

### CONCLUSION

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

DATED this 10 day of December, 2009.

Respectfully submitted,

  
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